Exhibit #2

SEP 2 7 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K052422

1. Submitter's Identification:

Flow X-Ray Corporation
420 Hempstead Turnpike
W. Hempstead, NY 11562
Tel: 516-485-7000

Contact: Mr. Peter Mitropoulos

Date Summary Prepared: August 31, 2005

2. Name of the Device:

EnVision Intraoral Dental X-Ray Machines (Wall Mounted and Mobile)

Common or Usual Name:

Intraoral Dental X-Ray Unit

3. Predicate Device Information:

K#896024, MDT/Castle Model HDX Dental X-Ray Machine; MDT Diagnostic Co., Rochester, NY

4. Device Description:

The EnVision Intraoral Dental X-Ray Machine (Wall Mounted and Mobile) is intended to be used for intraoral radiography of dental anatomy for diagnostic purposes performed by professionally trained and licensed personnel on the use of the system. Please note that the intended use of the EnVision Machine, as described in the labeling, has not changed as a result of the modification.

The reason for the modification is to minimize the potential error(s) an operator may make in selecting the desired x-ray exposure time(s) for different speed

image receptors, different teeth, different size patients, and different length cones.

The EnVision Intraoral Dental X-Ray Machine is a highly efficient user-friendly constant-potential output X-radiation system that produces, clear, sharp radiography with minimal elapsed exposure time. Includes 2 versions- integrated and remote, that are configured to operate on various line voltages, and equipped with a 20 cm SSD long round beam limiting device (30 cm round, and 20 and 20 cm rectangular SSD's available as optional).

5. **Intended Use:**

The EnVision Intraoral Dental X-Ray Machines (Wall Mounted and Mobile) are intended to be used only for intraoral radiography of dental anatomy for diagnostic purposes performed by professionally trained and licensed personnel on the use of the system.

6. **Comparison to Predicate Devices:**

The EnVision and HDX Dental X-Ray Machines (Wall Mounted and Mobile) are virtually identical in regard to the intended use and technology. In addition to manual exposure time selection in the HDX, a new feature of preset anatomical exposure time settings had been added to the EnVision Machine to reduce the possibility of operator error in selecting the proper exposure time for different teeth.

7. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes IEC 60601-1 and IEC 60601-1-2 requirements. In addition, ISO 14971: 2000, "Medical Devices – Application of Risk Management to Medical Devices Standard" was used for our Risk Assessment.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The subject device, the EnVision Intraoral Dental X-Ray Machine (Wall Mounted and Mobile) has identical indications for use as the original MDT/Castle Model HDX Dental X-Ray Machine. The bench testing and software validation documentation contained in our submission demonstrates that there are no

differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the EnVision Intraoral Dental X-Ray Machine (Wall Mounted and Mobile) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Flow X-Ray Corporation
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K052422
Trade/Device Name: EnVision Intraoral Dental X-Ray Machine (Wall Mounted and Mobile)
Regulation Number: 21 CFR 872.1810
Regulation Name: Intraoral source x-ray system
Regulatory Class: II
Product Code: EAP
Dated: September 1, 2005
Received: September 2, 2005

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K052422

Device Name: EnVision Intraoral Dental X-Ray Machine (Wall Mounted and Mobile)

Indications For Use:

The EnVision Intraoral Dental X-Ray Machines (Wall Mounted and Mobile) are intended to be used only for intraoral radiography of dental anatomy for diagnostic purposes performed by professionally trained and licensed personnel on the use of the system.

Prescription Use __X___
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use_____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052422